

Exhibit 1

SETTLEMENT AGREEMENT

This Settlement Agreement (Agreement) is entered into among: (1) the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (OIG-HHS) of the Department of Health and Human Services (HHS), the Defense Health Agency (DHA), acting on behalf of the TRICARE program, and the Office of Personnel Management (OPM), which administers the Federal Employees Health Benefits Program (FEHBP) (collectively, the “United States”); (2) Genova Diagnostics, Inc. (Genova); and (3) Darryl Landis, M.D. (Relator), through their authorized representatives. Collectively, all of the above will be referred to as “the Parties.”

RECITALS

A. Genova, a Delaware corporation with its main office in Asheville, North Carolina, provides clinical laboratory services for patients referred by physicians and other health care providers.

B. On December 15, 2017, Relator filed a *qui tam* action in the United States District Court for the Western District of North Carolina captioned *United States ex rel. Darryl Landis, M.D. v. Genova Diagnostics, Inc., et al.*, No. 1:17-cv-341, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the Civil Action).

C. The United States contends that Genova submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll (Medicare); the TRICARE Program, 10 U.S.C. §§ 1071-1110b (TRICARE); and the FEHBP, 5 U.S.C. §§ 8901-8914.

D. On March 21, 2018, the Centers for Medicare & Medicaid Services (CMS) suspended Genova’s Medicare payments pursuant to 42 C.F.R. § 405.371(a)(2) (CMS Suspension). The CMS Suspension remains in effect. On April 18, 2018, the DHA suspended

Genova's TRICARE payments pursuant to 32 C.F.R. § 199.9(h) (DHA Suspension). The DHA suspension remains in effect (together the CMS Suspension and the DHA Suspension are hereinafter referenced as "the Suspensions"). The term "CMS Suspended Amount" refers to the funds held in suspense of payment to Genova by CMS from the date of implementation of the suspension through the Effective Date of this Agreement. The term "DHA Suspended Amount" refers to the funds held in suspense of payment to Genova by DHA from the date of implementation of the suspension through the Effective Date of this Agreement. As of January 2020, the CMS Suspended Amount was approximately \$15,072,073, and the DHA Suspended Amount was approximately \$2,328,664.

E. The United States contends that it has certain civil claims against Genova arising from the following conduct:

- a. From January 1, 2013, through August 22, 2019, Genova submitted claims for the IgG allergen, NutrEval and GI Effects test profiles, which were not reimbursable because they were not medically necessary and not covered services under Medicare, TRICARE, or FEHBP;
- b. From January 1, 2013, through August 22, 2019, Genova submitted claims for multiple units of CPT Codes 86001, 83921 and 87798, for testing which was experimental/investigational and billed improperly by routinely appending Modifier 91 in order to bypass computer edits which resulted, at times, in claims being billed and paid in excess of medically unlikely edits;
- c. From January 1, 2013, through August 22, 2019, Genova submitted claims for unbundled services billed in conjunction with the organic acid component of the Metabolic Analysis Profile contained in the NutrEval panel tests (CPT 83921); and

d. Between June 22, 2010 and August 11, 2016, Genova paid compensation to phlebotomy vendors pursuant to three phlebotomy agreements that the Government alleges violated the physician self-referral prohibition of 42 U.S.C. § 1395nn (the “Stark Law”) as follows:

- (1) From June 22, 2010 through September 30, 2014, Genova made payments to Testing Solutions pursuant to a written phlebotomy agreement wherein Genova agreed to pay \$20.00 per patient for phlebotomy services performed in conjunction with diagnostic laboratory tests referred by the physician whose spouse owned Testing Solutions;
- (2) From October 16, 2013 through February 27, 2015, Genova made payments to phlebotomy vendor Perky Puncture, LLC (Perky Puncture) pursuant to a written phlebotomy agreement wherein Genova agreed to pay \$25.00 per patient for phlebotomy services performed in conjunction with diagnostic laboratory tests referred by the physician whose spouse owned Perky Puncture;
- (3) From March 25, 2014 through August 11, 2015, Genova made payments to Maverick Wellness pursuant to a written phlebotomy agreement wherein Genova agreed to pay \$30.00 per patient for phlebotomy services performed in conjunction with diagnostic laboratory tests referred by a physician owner of the practice who also was the owner of Maverick Wellness.

The Government alleges that payments made pursuant to the above-listed phlebotomy arrangements exceeded the fair market value of the services actually

performed by Testing Solutions, Perky Puncture, and Maverick Wellness. The United States also contends that the phlebotomy arrangements described above created compensation arrangements between Genova and the referring physicians and immediate family members of referring physicians who owned the phlebotomy vendors, and that these compensation arrangements did not satisfy any exception to the Stark Law or the regulations promulgated thereunder. The United States contends that Genova violated the False Claims Act at 31 U.S.C. § 3729, *et seq.*, when Genova presented claims to the Medicare Program for designated health services referred to Genova by the above-referenced physicians who had or whose immediate family members had compensation arrangements with Genova that did not satisfy the requirements of any applicable exception to the Stark Law.

As a result of the foregoing conduct, the United States alleges that Genova submitted false or fraudulent claims to Medicare, TRICARE, and FEHBP. The conduct set forth in Paragraph E is referred to below as the “Covered Conduct.”

F. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relator’s reasonable expenses, attorneys’ fees and costs.

G. This Settlement Agreement is neither an admission of liability by Genova nor a concession by the United States that its claims are not well founded. Genova denies all allegations made by Relator and denies that it engaged in the Covered Conduct.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Genova shall pay to the United States the sums specified in this paragraph (collectively, the Settlement Amount), under the terms and conditions specified herein:
 - a. Genova shall forfeit any and all right or claim to the CMS Suspended Amount and DHA Suspended Amount (collectively, the “Initial Payment Amount”), and the United States shall apply the Initial Payment Amount in partial satisfaction of Genova’s payment of the Settlement Amount. Genova expressly relinquishes any and all rights of any kind that it has with respect to the CMS Suspended Amount and DHA Suspended Amount, including but not limited to: any and all rights to have an overpayment determined under any statute, regulation or rule; any and all rights to payment of the CMS Suspended Amount and DHA Suspended Amount; any and all rights to appeal, whether formally or informally and whether administratively or judicially, the right of the United States and/or CMS and/or DHA to retain the CMS Suspended Amount and DHA Suspended Amount; and any other rights Genova may have to challenge the withholding of the Suspended Amount or the Suspensions in any respect.
 - b. If, within any year of the five (5) year period commencing on the first day of the month immediately following the Effective Date of this Settlement Agreement (each year of which is a “Measurement Period”), Genova’s annual net revenue (including the revenue of any other property, entity, or venture in which Genova has, or subsequently acquires, an ownership interest) for such Measurement Period exceeds One Hundred Million Dollars (\$100,000,000.00), Genova shall pay the United States an amount

equal to thirteen percent (13%) of annual net revenue above One Hundred Million Dollars (\$100,000,000.00) for such Measurement Period (each a “Revenue Payment”). Within one hundred twenty (120) days of the end of each Measurement Period, Genova shall submit to the Department of Justice, Civil Division, annual financial statements and any other reasonably requested supporting documentation (Annual Financials) certified by Genova’s CFO and CEO for the purposes of calculating the Revenue Payments. Genova shall pay any owed Revenue Payments to the United States by electronic funds transfer, pursuant to written instructions by the United States, within one hundred fifty (150) days of the end of each Measurement Period. As used in this Agreement, “net revenue” is defined as set forth in and used for purposes of Genova’s audited financial statements and consistent with Generally Accepted Accounting Principles (GAAP).

- c. Genova agrees to provide fifteen (15) business days advance, written notice to the United States of any sale, transfer, merger, or liquidation of assets of Genova (or any other property, entity, or venture in which Genova has an ownership interest) in excess of \$1 million in any of the first five years after the Effective Date (Sale Event). Upon the occurrence of a Sale Event, Genova shall make an additional payment to the United States by electronic funds transfer, pursuant to written instructions by the United States, within seven (7) business days of the closing on the Sale Event, of twenty- percent (20%) of the following amount: the total proceeds from the Sale Event less (i) state, federal, and local taxes; (ii)

repayment of Genova's secured debt obligations in an amount no more than that debt which existed as of the Effective Date pursuant to the Bank of Montreal Credit Agreement dated November 13, 2013 (as amended) that had not been satisfied as of the date of the Sale Event; and (iii) and reasonable and necessary transaction fees directly incurred by Genova paid to non-related parties in effectuating the Sale Event (Sale Event Payment). Upon finalization of this Agreement, Genova's CEO and CFO will provide and certify as truthful and accurate the amount outstanding pursuant to the Bank of Montreal Credit Agreement dated November 13, 2013 (as amended) as of the Effective Date.

- d. Within five years of the Effective Date of this Agreement, if Genova obtains any insurance coverage for any payments relating to the substance of litigation, disputes, or claims relating to the government's investigation and/or the Covered Conduct (excluding coverage for legal fees and expenses), Genova shall also pay to the United States Seventy-Five percent (75%) of the amount of each such insurance payment, within ten (10) business days of the date that the payment is made to, or on behalf of, Genova. Genova will request coverage under any applicable insurance policy. Following the Effective Date of this Agreement and for five years thereafter, Genova will annually notify the Civil Division of the United States Department of Justice in writing of each such request under this subparagraph.

- e. All payments by Genova under subparagraphs (a)-(d) up to Thirty Million, Six Hundred Thousand Dollars (\$30,600,000.00) are restitution to the United States.
- f. Genova shall have no obligation to make any payment pursuant to subparagraphs (b)-(d) in excess of Twenty-Six Million Dollars (\$26,000,000.00), in the aggregate.

2. Conditioned upon the United States' receipt of the Settlement Amount payments, the United States agrees that it shall make payments to the Relator as described in this paragraph (collectively, the Relator's Share):

- a. The United States agrees that it shall pay to Relator by electronic funds transfer fifteen percent (15%) of the CMS Suspended Amount and fifteen percent (15%) of the DHA Suspended Amount as soon as feasible after the Effective Date of the Agreement.
- b. Conditioned upon the United States' receipt of any payment from Genova under Paragraph 1(b), 1(c), or 1(d) of this Agreement, the United States agrees that it shall pay to Relator by electronic funds transfer fifteen percent (15%) of each such payment received under the Agreement as soon as feasible after receipt of the payment.

3. Subject to the exceptions in Paragraph 8 (concerning reserved claims) below, and subject to Paragraph 11 (concerning disclosure of assets), Paragraph 20 (concerning default), and Paragraph 21 (concerning bankruptcy) below, and upon the United States' receipt of the Initial Payment Amount, the United States releases Genova from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil

Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, and fraud.

4. Subject to the exceptions in Paragraph 8 (concerning reserved claims) below, and subject to Paragraph 11 (concerning disclosure of assets), Paragraph 20 (concerning default), and Paragraph 21 (concerning bankruptcy) below, and upon the United States' receipt of the Initial Payment Amount, Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, releases Genova from any civil monetary claim the Relator has on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733.

5. In consideration of the obligations of Genova in this Agreement and the Corporate Integrity Agreement (CIA), entered into between OIG-HHS and Genova, and conditioned upon Genova's full payment of the Initial Payment Amount, the OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Genova under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in this Paragraph and in Paragraph 8 (concerning reserved claims), below. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Genova from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 8, below.

6. In consideration of the obligations of Genova set forth in this Agreement, and upon the United States' receipt of the Initial Payment Amount, DHA shall release and refrain

from instituting, directing, or maintaining any administrative action seeking exclusion from the TRICARE Program against Genova under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in this paragraph and in Paragraph 8 (concerning reserved claims), below. DHA expressly reserves authority to exclude Genova from the TRICARE Program under 32 C.F.R. §§ 199.9 (f)(1)(i)(A), (f)(1)(i)(B), and (f)(1)(iii) (mandatory exclusion), based upon the Covered Conduct. Nothing in this paragraph precludes DHA or the TRICARE Program from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 8, below.

7. In consideration of the obligations of Genova in this Agreement, and upon the United States' receipt of the Initial Payment Amount, OPM agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the FEHBP against Genova under 5 U.S.C. § 8902a or 5 C.F.R. Part 890 Subpart J or Part 919 for the Covered Conduct, except as reserved in this paragraph and in Paragraph 8 (concerning reserved claims), below, and except if excluded by the OIG-HHS pursuant to 42 U.S.C. § 1320a-7(a). OPM expressly reserves all rights to comply with any statutory obligation to debar Genova from the FEHBP under 5 U.S.C. § 8902a(b) (mandatory exclusion) based upon the Covered Conduct. Nothing in this paragraph precludes OPM from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 8, below.

8. Notwithstanding the releases given in Paragraphs 3 through 7 of this Agreement, or any other term of this Agreement, the following claims and rights of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;

- c. Except as explicitly stated in this Agreement, any administrative liability or enforcement right, including mandatory exclusion from Federal health care programs;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement;
- f. Any liability of individuals;
- h. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- i. Any liability for failure to deliver goods or services due;
- j. Any liability for fraudulent transfer or conveyance; and
- k. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

9. Relator and his heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon Relator's receipt of the Relator's Share, Relator and his heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil Action or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Action.

10. In consideration of the payments to be made to Relator as set forth in Paragraph 2 herein, Relator, for himself and his heirs, successors, attorneys, agents, and assigns, releases all

defendants in the Civil Action, and (as applicable) their or its respective parents, subsidiaries and affiliates; successors and predecessors; shareholders and employees; and assigns, from any liability to Relator arising from the filing of the Civil Action. Relator, for himself and his heirs, successors, attorneys, agents and assigns, releases Genova; GNVA Holdings, Inc.; GNVA Equity Holdco., LLC; GNVA Intermediate Holdings, LLC; GNVA Parent, LLC; Levine Leichtman Capital Partners V, L.P.; Levine Leichtman Capital Partners, LLC, Arthur Levine, Lauren Leichtman; Aaron Perlmutter, and Chris Smith and (as applicable) their or its respective parents, subsidiaries and affiliates; holding companies, successors and predecessors; shareholders, partners (limited and general), and employees; and assigns (collectively “Releasees”), from all statutory and common law claims, whether now known and unknown, contingent and non-contingent, that he had or now has, including without limitation, claims arising out of or in any way related to his employment at Genova and relationship with Releasees or otherwise, including but not limited to the termination of his employment, and including but not limited to those claims arising under the Age Discrimination in Employment Act of 1967 (ADEA) as amended, the Older Workers Benefit Protection Act of 1990 (OWBPA), Title VII of the Civil Rights Act of 1964 as amended, the Civil Rights Act of 1991, the Equal Pay Act of 1963, the Americans with Disabilities Act of 1990 as amended, the Worker Adjustment and Retraining Notification Act of 1988, the U.S. Sarbanes Oxley Act of 2002, Sections 748(h)(1), 922(h)(1) and 1057 of the Dodd-Frank Wall Street Reform and Consumer Protection Act, the Family and Medical Leave Act of 1993 as amended, the Employee Retirement Income Security Act of 1974 as amended, the North Carolina Equal Employment Practices Act, the North Carolina Persons With Disabilities Protection Act, the North Carolina Retaliatory Employment Discrimination Law, the North Carolina Labor Law, the North Carolina Wage and Hour Act, the North Carolina Workplace Violence Prevention Act, the North Carolina Parent Involvement Leave law, and any other state and local laws applicable to him, or

any other federal, state or local statute or ordinance and all amendments thereto. Further, Relator expressly recognizes and agrees that, by entering into this Agreement, he is waiving any and all rights or claims that he may have arising under the ADEA, as amended by the OWBPA, which have arisen on or before the date of the execution of this Agreement. Notwithstanding the above, the releases agreed to by Relator as provided herein do not release Genova from its Promissory Note obligations to Mustard Seed Venture Partners, LLC, an affiliate of Relator. By his signature below, Relator warrants and represents that (a) in return for his execution of this Agreement, he will receive consideration beyond any entitlement he may have had before entering this Agreement; (b) he was advised to consult with an attorney before signing this Agreement; (c) he has been given twenty-one (21) days to review this ADEA release and waiver and seven (7) days to revoke it; and, (d) he has voluntarily elected to execute this Agreement. In the event he wishes to revoke this Agreement, he must provide written notice of revocation to Earlene Clark at Genova at 63 Zillicoa Street, Asheville, North Carolina, 28801, EClark@gdx.net by email and certified mail or overnight mail via a nationally recognized mail provider, with a copy emailed to Arthur J. Fried, afried@ebglaw.com, no later than 5:00 p.m. on or before the seventh day after he has signed the Agreement.

a. Relator acknowledges that there is a risk that subsequent to the execution of this Agreement, he will become aware of a claim, as described above, against Releasees, inclusive, without limitation, of any damage, loss or injury to persons or property, that is unknown or unanticipated at the time of the execution of this Agreement. By executing this Agreement, Relator hereby specifically assumes such risk and agrees that this Agreement and the releases contained herein shall and do apply to all unknown or unanticipated results of any and all such matters, as well as those currently known or anticipated. Accordingly, Relator acknowledges that he has read the provisions of California Civil Code §1542, which provides as follows:

A general release does not extend to claims that the creditor or releasing party does not know or suspect to exist in his or her favor at the time of executing the release and that, if known by him or her, would have materially affected his or her settlement with the debtor or released party.

Relator, for himself and his heirs, successors, attorneys, agents and assigns, expressly waives, relinquishes and forfeits all rights and benefits accorded by the provisions of California Civil Code §1542, and furthermore waives any rights he might have to invoke said provisions now or in the future with respect to the Releasees.

11. Genova has provided a sworn Financial Statement of Corporate Disclosure and supplementary documentation (Financial Statements) to the United States and the United States has relied on the accuracy and completeness of those Financial Statements in reaching this Agreement. Genova warrants that the Financial Statements are complete, accurate, and current as of this Agreement, except as to projections and other forward-looking statements provided as part of their submission. If the United States learns of asset(s) in which Genova had an interest of any kind at the time of this Agreement that were not disclosed in the Financial Statements, or if the United States learns of any false statement or misrepresentation by Genova on, or in connection with, the Financial Statements, and if such nondisclosure or misrepresentation changes the estimated net worth set forth in the Financial Statements by \$1,530,000 or more, the United States may at its option: (a) rescind this Agreement and file suit based on the Covered Conduct, or (b) let the Agreement stand and collect the full Settlement Amount in accordance with the Agreement plus one hundred percent (100%) of the value of the net worth of Genova's previously undisclosed assets. Genova agrees not to contest any collection action undertaken by the United States pursuant to this provision, and agrees that it will pay the United States the greater of (i) a ten-percent (10%) surcharge of the amount collected, as allowed by 28 U.S.C. § 3011(a), or (ii) the United States' reasonable attorneys' fees and expenses incurred in such an

action. In the event that the United States, pursuant to this paragraph rescinds this Agreement, Genova waives and agrees not to plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that (a) are filed by the United States within 120 calendar days of written notification to Genova that this Agreement has been rescinded, and (b) relate to the Covered Conduct, except to the extent these defenses were available on December 15, 2017.

12. Genova waives and shall not assert any defenses Genova may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

13. Genova fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Genova has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

14. Genova and GNVA Holdings, Inc., GNVA Equity Holdco, LLC, GNVA Intermediate Holdings, LLC, GNVA Parent, LLC, Levine Leichtman Capital Partners V, L.P. Levine Leichtman Capital Partners, LLC, Arthur Levine, Lauren Leichtman, Aaron Perlmutter, and Chris Smith (collectively "Relator Releasees") release Relator from all statutory and common law claims, now known, contingent and non-contingent, that they had or now have, whether arising out of or in any way related to Relator's employment at Genova and Relator's

relationship with Relator Releasees or otherwise. For the avoidance of doubt, nothing in this paragraph shall limit Relator Releasees' rights to implead, file a third party complaint against or seek indemnification and/or contribution from Relator in connection with any claims unknown to Relator Releasees as of the date of this Settlement Agreement. The undersigned Relator Releasees warrant and represent that they have full authority to execute this Release on behalf of all enumerated Relator Releasees.

15. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier), TRICARE carrier or payer, FEHBP carrier or payor, or any state payer, related to the Covered Conduct; and Genova agrees not to resubmit to any Medicare contractor, TRICARE carrier or payer, FEHBP carrier or payor, or any state payer any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

16. Genova agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395lll and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Genova, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' audit(s) and civil investigation(s) of the matters covered by this Agreement;
- (3) Genova's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in

connection with the matters covered by this Agreement (including attorneys' fees);

- (4) the negotiation and performance of this Agreement;
- (5) the payment Genova makes to the United States pursuant to this Agreement and any payments that Genova may make to Relator, including costs and attorneys' fees; and
- (6) the negotiation of, and obligations undertaken pursuant to the CIA to:
 - (i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and (ii) prepare and submit reports to the OIG-HHS

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and FEHBP (hereinafter referred to as Unallowable Costs). However, nothing in Paragraph 16(a)(6) that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to Genova.

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Genova, and Genova shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Genova or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Genova further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors,

and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Genova or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. Genova agrees that the United States, at a minimum, shall be entitled to recoup from Genova any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Genova or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on Genova or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Genova's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

17. Genova agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Genova shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use reasonable efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights

and privileges of such individuals. Genova further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

18. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 19 (waiver for beneficiaries paragraph), below, and Paragraph 10, above.

19. Genova agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

20. The Settlement Amount represents the amount the United States is willing to accept in compromise of its civil claims arising from the Covered Conduct due solely to Genova's financial condition as reflected in the Financial Statements referenced in Paragraph 11.

a. In the event that Genova fails to pay any amount as provided within Paragraph 1 by the date on which such payment is due, Genova shall be in Default of its payment obligations (Default). The United States will provide a written Notice of Default, and Genova shall have an opportunity to cure such Default within seven (7) business days from the date of receipt of the Notice of Default by making the payment due under the payment schedule and paying any additional interest accruing under the Settlement Agreement up to the date of payment. Notice of Default will be delivered to Genova, or to such other representative as Genova shall designate in advance in writing. If Genova fails to cure the Default within seven (7) business days of receiving the Notice of Default, and in the absence of an agreement with the United States to a modified payment schedule (Uncured Default), any unpaid balance of the Settlement Amount

which is then due and owing shall become immediately due and payable, and interest on any such unpaid balance shall thereafter accrue at the rate of twelve percent (12%) per annum, compounded daily from the date of Default, on the unpaid total (principal and interest balance).

b. If Genova fails to provide its Annual Financials as required by Paragraph 1(b), the United States will notify Genova in writing of the failure. If Genova fails to remedy such failure within thirty (30) calendar days from the date of receipt of the United States' written notice, Genova shall be in Uncured Default. If Genova fails to provide the advance, written notice of a Sale Event as required by Paragraph 1(c), it shall be in Uncured Default.

c. In the event of Uncured Default, Genova agrees that the United States, at its sole discretion, may (i) declare this Agreement breached and proceed against Genova for any claims, including those to be released by this agreement; (ii) take any action to enforce this Agreement in a new action or by reinstating the Civil Action; (iii) offset the remaining unpaid balance from any amounts due and owing to Genova and/or affiliated companies by any department, agency, or agent of the United States at the time of Default or subsequently; and/or (iv) exercise any other right granted by law, or under the terms of this Agreement, or recognizable at common law or in equity. At its sole option, the United States may retain any payments previously made, rescind this Agreement and pursue the Civil Action or bring any civil and/or administrative claim, action, or proceeding against Genova for the claims that would otherwise be covered by the releases provided in Paragraphs 3 through 7 above, with any recovery reduced by the amount of any payments previously made by Genova to the United States under this Agreement. The United States shall be entitled to any other rights granted by law or in equity by reason of Default, including referral of this matter for private collection. In the event the United States pursues a collection action, Genova agrees immediately to pay the United States the greater of: (i) a ten-percent (10%) surcharge of the amount collected, as allowed by 28 U.S.C. § 3011(a); or

(ii) the United States' reasonable attorneys' fees and expenses incurred in such an action. In the event that the United States opts to rescind this Agreement pursuant to this paragraph, Genova waives and agrees not to plead, argue, or otherwise raise any defenses of statute of limitations, laches, estoppel or similar theories, to any civil or administrative claims that are: (i) filed by the United States against Genova within 120 days of written notification that this Agreement has been rescinded; and (ii) relate to the Covered Conduct, except to the extent these defenses were available on the Effective Date of the Agreement. Genova agrees not to contest any offset, recoupment, and/or collection action undertaken by the United States pursuant to this paragraph, either administratively or in any state or federal court, except on the grounds of actual payment to the United States.

d. Notwithstanding the foregoing, including Paragraph 5, in the event of Uncured Default, OIG-HHS may exclude Genova from participating in all Federal health care programs until Genova pays the portion of any Contingent Payment which is then due and owing, with interest, as set forth above. OIG-HHS will provide written notice of any such exclusion to Genova. Genova waives any further notice of the exclusion under 42 U.S.C. § 1320a-7(b)(7), and agrees not to contest such exclusion either administratively or in any state or federal court. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, Genova wishes to apply for reinstatement, it must submit a written request for reinstatement to OIG-HHS in accordance with the provisions of 42 C.F.R. §§ 1001.3001-.3005. Genova will not be reinstated unless and until OIG-HHS approves such request for reinstatement. The option for Exclusion for Default as defined in this paragraph is in addition to, and not in lieu of, the options identified in this Agreement or otherwise available.

21. In exchange for valuable consideration provided in this Agreement, Genova acknowledges the following.

a. Genova has reviewed its financial situation and warrants that it is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I) and shall remain solvent for at least ninety-one (91) days after the Effective Date.

b. In evaluating whether to execute this Agreement, the Parties intend that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to Genova, within the meaning of 11 U.S.C. § 547(c)(1), and the Parties conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange.

c. The mutual promises, covenants, and obligations set forth herein are intended by the Parties to, and do in fact, constitute a reasonably equivalent exchange of value.

d. The Parties do not intend to hinder, delay, or defraud any entity to which Genova was or became indebted to on or after the date of any transfer contemplated in this Agreement, within the meaning of 11 U.S.C. § 548(a)(1).

e. If Genova's obligations under this Agreement are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, or if, before the earlier of the date that the Settlement Amount is paid in full or the end of the five (5) year period commencing on the Effective Date, Genova or a third party commences a case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors (i) seeking any order for relief of Genova's debts, or to adjudicate Genova as bankrupt or insolvent; or (ii) seeking appointment of a receiver, trustee, custodian, or other similar official for Genova or for all or any substantial part of Genova's assets, the United States (a) may rescind the releases in this Agreement and bring any civil and/or administrative claim, action, or proceeding against Genova for the claims that would otherwise be covered by the releases provided in Paragraphs 3 through 7 above; and (b) the

United States has an undisputed, noncontingent, and liquidated allowed claim against Genova in the amount of \$156,715,470.00, less any payments received pursuant to this agreement, provided, however, that such payments are not otherwise avoided and recovered by Genova, a receiver, trustee, custodian, or other similar official for Genova.

f. Genova agrees that any such civil and/or administrative claim, action, or proceeding brought by the United States is not subject to an “automatic stay” pursuant to 11 U.S.C. § 362(a) because it would be an exercise of the United States’ police and regulatory power. Genova shall not argue or otherwise contend that the United States’ claim, action, or proceeding is subject to an automatic stay and, to the extent necessary, consents to relief from the automatic stay for cause under 11 U.S.C. § 362(d)(1). Genova waives and shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claim, action, or proceeding brought by the United States within 120 days of written notification to Genova that the releases have been rescinded pursuant to this paragraph, except to the extent such defenses were available on December 15, 2017.

22. After the Effective Date, the United States and the Relator shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal of the Claims Against Genova in the Civil Action pursuant to Rule 41(a)(1), and, with respect to the Relator, against the Releasees. The Joint Stipulation of Dismissal shall be with prejudice as to the United States’ and the Relator’s claims in the Civil Action against Genova as to the Covered Conduct and consistent with the terms and conditions of this Agreement. The Joint Stipulation of Dismissal shall be without prejudice to the United States as to all other claims against Genova and as to any claim(s) against the other defendants in the Civil Action, and shall be with prejudice to the Relator as to the Releasees.

23. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

24. Each Party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

25. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the Western District of North Carolina. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

26. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties. Forbearance by the United States from pursuing any remedy or relief available to it under this Agreement shall not constitute a waiver of rights under this Agreement.

27. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

28. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

29. This Agreement is binding on Genova's successors, transferees, heirs, and assigns.

30. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.

31. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

32. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: _____

BY: MICHAEL HOFFMAN
MICHAEL A. HOFFMAN
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

Digitally signed by MICHAEL HOFFMAN
Date: 2020.04.17 17:03:52 -04'00'

DATED: _____

BY: KATHERINE ARMSTRONG
KATHERINE T. ARMSTRONG
Assistant United States Attorney
United States Attorney's Office
Western District of North Carolina

Digitally signed by KATHERINE ARMSTRONG
Date: 2020.04.20 06:21:37 -04'00'

DATED: _____

BY: _____
LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DATED: _____

BY: _____
BRYAN T. WHEELER
Acting General Counsel
Defense Health Agency
United States Department of Defense

DATED: _____

BY: _____
EDWARD M. DEHARDE
Assistant Director of Federal Employee
Insurance Operations
Healthcare and Insurance
United States Office of Personnel Management

DATED: _____

BY: _____
PAUL ST. HILLAIRES
Assistant Inspector General
for Legal & Legislative Affairs
Office of the Inspector General
United States Office of Personnel Management

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____
MICHAEL A. HOFFMAN
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____

BY: _____
KATHERINE T. ARMSTRONG
Assistant United States Attorney
United States Attorney's Office
Western District of North Carolina

DATED: _____

BY: _____
GREGORY
DEMSKE
Digitally signed by GREGORY
DEMSKE
Date: 2020.04.17 07:27:36 -04'00'
LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DATED: _____

BY: _____
BRYAN T. WHEELER
Acting General Counsel
Defense Health Agency
United States Department of Defense

DATED: _____

BY: _____
EDWARD M. DEHARDE
Assistant Director of Federal Employee
Insurance Operations
Healthcare and Insurance
United States Office of Personnel Management

DATED: _____

BY: _____
PAUL ST. HILLAIRE
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Office of the Inspector General
United States Office of Personnel Management

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Commercial Litigation Branch
Civil Division
United States Department of Justice


DATED: _____

BY: _____
KATHERINE T. ARMSTRONG
Assistant United States Attorney
United States Attorney's Office
Western District of North Carolina

DATED: _____

BY: _____
LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DATED: 04/17/2020

BY: BLEY.PAUL.NICHOLAS.10998738
LAS.1099873821

~~RYAN T. WHEELER~~ SALVATORE M. MAIDA
for Acting General Counsel
Defense Health Agency
United States Department of Defense

DATED: _____

BY: _____
EDWARD M. DEHARDE
Assistant Director of Federal Employee
Insurance Operations
Healthcare and Insurance
United States Office of Personnel Management

DATED: _____

BY: _____
PAUL ST. HILLAIRES
Assistant Inspector General
for Legal & Legislative Affairs
Office of the Inspector General
United States Office of Personnel Management

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____
MICHAEL A. HOFFMAN
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____

BY: _____
KATHERINE T. ARMSTRONG
Assistant United States Attorney
United States Attorney's Office
Western District of North Carolina

DATED: _____

BY: _____
LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DATED: _____

BY: _____
BRYAN T. WHEELER
Acting General Counsel
Defense Health Agency
United States Department of Defense

DATED: _____

BY: _____
EDWARD M. DEHARDE
Assistant Director of Federal Employee
Insurance Operations
Healthcare and Insurance
United States Office of Personnel Management

DATED: 4/14/2020

BY: **PAUL ST HILLAIRE**
Digitally signed by PAUL ST HILLAIRE
DN: c=US, o=U.S. Government, ou=Office of Personnel
Management, cn=PAUL ST HILLAIRE,
0.9.2342.19200300.100.1.1=24001000034787
Date: 2020.04.14 17:45:25 -04'00'
PAUL ST. HILLAIRE
Assistant Inspector General
for Legal & Legislative Affairs
Office of the Inspector General
United States Office of Personnel Management

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____
MICHAEL A. HOFFMAN
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____

BY: _____
KATHERINE T. ARMSTRONG
Assistant United States Attorney
United States Attorney's Office
Western District of North Carolina

DATED: _____

BY: _____
LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DATED: _____

BY: _____
BRYAN T. WHEELER
Acting General Counsel
Defense Health Agency
United States Department of Defense

DATED: _____

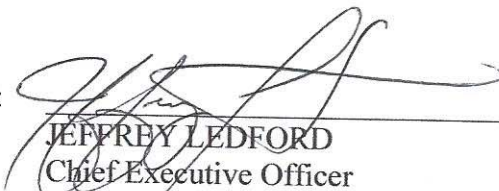
BY: EDWARD DEHARDE
Digitally signed by EDWARD DEHARDE
DN: cn=U.S. Government, ou=Office of Personnel Management,
c=EDWARD DEHARDE, o.9.2342.19200300.100.1.1=24001000012935
Date: 2020.04.15 17:04:23 -0400
EDWARD M. DEHARDE
Assistant Director of Federal Employee
Insurance Operations
Healthcare and Insurance
United States Office of Personnel Management

DATED: _____

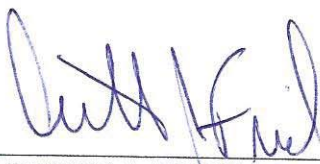
BY: _____
PAUL ST. HILLAIRES
Assistant Inspector General
for Legal & Legislative Affairs
Office of the Inspector General
United States Office of Personnel Management

GENOVA DIAGNOSTICS, INC.

DATED: 13 APR 20

BY: 
JEFFREY LEDFORD
Chief Executive Officer

DATED: 4/17/20


BY: 
ARTHUR J. FRIED
Epstein Becker & Green, P.C.
Counsel for Genova Diagnostics, Inc.

RELATOR DARRYL LANDIS, M.D.

DATED: 4/10/20

BY: 
DARRYL LANDIS, M.D.

DATED: 4/16/20

BY: 
SANDRA L.W. MILLER
CATHERINE F. WRENN
BRENT F. POWELL
Womble Bond Dickinson (US) LLP
Counsel for Relator Darryl Landis, M.D.